DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 3, 2015

Coloplast A/S
% Brian Schmidt
Regulatory Affairs Manager
Coloplast Corp.
1601 West River Road North
Minneapolis, MN 55411

Re: K140310
Trade/Device Name: Peristeen™ Anal Irrigation System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT, FCE
Dated: July 23, 2015
Received: July 27, 2015

Dear Brian Schmidt,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140310

Device Name
Peristeen™ Anal Irrigation System

Indications for Use *(Describe)*
The Peristeen Anal Irrigation System is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2 years -<12 years old), adolescent (12 years - <18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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1. 510(K) SUMMARY OR 510(K) SUMMARY STATEMENT

510(k) Summary

510(K) Owner's Name: Coloplast A/S

Address: Holtedam 1
3050 Humlebaek, Denmark
Establishment Registration: 9610694
Owner/Operator: 8010144

Name of Contact Person: Brian Schmidt
Regulatory Affairs Manager

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Minneapolis, MN 55411

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Date Prepared: February 4, 2014

Trade Name: Peristeen™ Anal Irrigation System

Common Name: Rectal Catheter and accessories and
Enema kit

Classification Name: 876.5980 Gastrointestinal tube & accessories
Class II and
876.5210 Enema kit
Class I (Exempt)

Product Code: KNT and FCE

Legally Marketed Devices To Which Your Firm Is Claiming Equivalence:
The Peristeen™ Anal Irrigation System is substantially equivalent in performance, indications, design and materials to the Peristeen™ Anal Irrigation System cleared on June 8, 2012 under premarket notification 510(k) number K112860.

Indications for Use
The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21

years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Device Description

The Peristeen™ Anal Irrigation (PAI) System is a Class II device intended for intermittent use that facilitates emptying of the colon/bowel in patients with neurogenic bowel dysfunction. The PAI system consists of a single-use irrigation catheter that incorporates an inflatable balloon to keep the catheter in place during the procedure and retain the water that flows into the colon. The rectal catheter is non-sterile, intended for single-use, and packaged and labeled accordingly. The other components may be used multiple times; usage guidelines are detailed in the labeling. All System components are also provided separately in various accessory packages.

No changes have been made to the device design, materials, components, technological characteristics or manufacturing processes of the subject device compared to the predicate.

PAI System Performance Testing Summary

No change is being made to the predicate device. The subject device is identical to the previously clear device, Peristeen Anal Irrigation System (K083770, K103254, and K112860). The only change being effected is release of an updated IFU. As such, testing for Performance, Shelf Life and Biocompatibility was not deemed necessary to support substantial equivalence.

Substantial Equivalence Conclusion

No clinical testing was performed, referenced, or relied on in the 510(k) for a determination of substantial equivalence. Based upon the device comparisons, the PAI System is substantially equivalent in performance, indications, design, and materials to the Coloplast Peristeen™ Anal Irrigation (PAI) system cleared on June 8, 2012 under premarket notification 510(k) number K112860.